

STEPHAN W. NORSTED, PH.D., M.P.H.

Dr. Steve Norsted is a Founder of RCRI, Inc. and a Sr. Principal Advisor in worldwide regulatory and clinical affairs. He holds a Ph.D. and an M.P.H. in Epidemiology and has been responsible for the design, conduct and analysis of preclinical and clinical studies since 1980. He joined the medical device industry in 1988 and has held senior-level positions in Regulatory Affairs/Clinical Studies. Steve served as an Epidemiologist for the Washington State Health Department, and is currently an instructor on preclinical and clinical studies for the graduate schools of three universities.

Steve is a member of Regulatory Affairs Professional Society (RAPS) and has twice served as Co-Chairperson of the Clinical Studies Committee for Medical Alley. He lectures on clinical research methods and regulatory affairs at regional and national conferences.

EDUCATION:

Ph.D.	1987	Epidemiology, University of Texas, Houston, TX
M.P.H.	1981	Epidemiology, University of Minnesota, Minneapolis, MN
B.A.	1978	Psychology, University of Minnesota, Minneapolis, MN

PROFESSIONAL ACTIVITIES, HONORS AND DISTINCTIONS:

Advisory Board Member, Research Services Organization, University of Minnesota, Minneapolis, Minnesota 1999-2000
Patent: Method for Treating Benign Prostatic Hyperplasia with Thermal Therapy, Patent Number: 5,843,144; December 1, 1998

Grants/Contracts Awarded:

Sponsoring Agency: Centers for Disease Control (1986, 1987); "Population-based Birth Defects Surveillance"

Sponsoring Agency: Centers for Disease Control (1984); "Diabetes Control Program"

Sponsoring Agency: Texas Department of Labor and Standards (1982, 1983); "Texas Indoor Air Quality Study"

Member: Medical Alley; Co-Chairperson, Clinical Studies Committee

Regulatory Affairs Professionals Society, Washington D.C.

APPOINTMENTS:

Consulting Faculty, St. Cloud State University. Center for Regulatory Affairs. College of Science and Engineering. 2006.
Instructor, "Performing Medical Device Clinical Research". University of St. Thomas. College of Business. 2005, 2006.
Guest Instructor, "Experimental Paradigms in Medical Products Research". University of Minnesota, Bioengineering Department. 2003, 2004, 2005, 2006.
Guest Instructor, "Clinical Research Methods", "Epidemiology", "Biostatistics": University of Minnesota School of Public Health (1981, 1987, 1988)
Guest Instructor, "Epidemiology", "Biostatistics": University of Texas School of Public Health (1981, 1982, 1983)

LECTURES:

"Physician-Initiated Research Issues". Panelist. Presented April 19, 2006, Medical Alley. Minneapolis, MN.
"Statistics for Non-statisticians". Presented September 22, 2005, Sponsored by Society of Clinical Research Associates. 14th Annual Conference, Orlando, FL.
"Research Paradigms". Presented September 25, 2004. Sponsored by Society of Clinical Research Associates. 13th Annual Conference, Montreal, Canada.
"The Art and Science of Designing Successful Medical Device Clinical Trials Workshop". Presented June 24, 2004. Sponsored by MedEdge Conference, Minneapolis, MN.
"Design of Hardcopy and Electronic Case Report Forms." Presented January 15, 2003. Sponsored by Medical Alley, Minneapolis, MN
"Meeting the Clinical Requirements: Devices." RAPS certification preparatory conference: Principles and Practices of US Regulatory Affairs. Presented September 9, 2002. Sponsored by the Regulatory Affairs Professional Society, Minneapolis, MN
"The Art and Science of Designing Successful Medical Device Clinical Trials Workshop", September 13, 2001, Medical Devices & Diagnostics, San Diego, CA
"Clinical Research 101", February 21, 2001, Medical Alley, Minneapolis, MN
"Clinical Studies 102: Practical Statistics for Medical Product Clinical Trials", November 15, 2000, Medical Alley, Minneapolis, MN
"Medical Device Regulation Update", February 3, 2000, Minnesota Veterinary Medical Association, Bloomington, MN

"Structuring IDE Studies-Do It Once and Do It Right", Session II, January, 2000, Medical Design & Manufacturing, Anaheim, CA
"Structuring IDE Studies-Do It Once and Do It Right", Session I, October, 1999, Medical Design & Manufacturing, Minneapolis, MN
"Designing Case Report Forms", March, 1999, Medical Alley, Minneapolis, MN
"The Art and Science of Designing Successful Medical Device Clinical Trials", June 22, 1998, Institute for International Research, Minneapolis, MN
"Study Designs Used in Medical Device Trials", February, 1998, Medical Alley, Minneapolis, MN
"Practical Challenges of Clinical Trial Design for Medical Devices", April, 1997, Medical Alley, Minneapolis, MN
"Fundamental Responsibilities of Clinical Trial Design for Medical Devices", 1997.
"Challenges to the Medical Device Industry", December, 1994, Medical Alley, Minneapolis, MN
"Pretesting of Case Report Forms", August, 1994, Medical Alley, Minneapolis, MN
"Sample Size Estimation", April, 1993, Institute for International Research, Philadelphia, PA
"Meeting the Clinical Requirements: Devices. RAPS certification preparatory conference: Principles and Practices of US Regulatory Affairs. Presented September 9, 2002. Sponsored by the Regulatory Affairs Professional Society. Minneapolis, MN

PUBLICATIONS:

Lehmann MH, Thomas A, Nabih MA, Steinman RT, Fromm BS, Shah M, Norsted SW. Sudden death in recipients of first-generation implantable cardioverter defibrillators: analysis of terminal events. *J Interv Cardiol* 7(5):1-17 (1994).

Sprafka JM, Norsted SW, Folsom AR, Burke GL, Luepker RV. Life-style Factors Do Not Explain Racial Differences in High Density Lipoprotein Cholesterol: The Minnesota Heart Survey. *Epidemiology* 3:156-163 (1992).

Folsom AR, Cook TC, Sprafka JM, Burke GL, Norsted SW, Jacobs DR. Differences in leisure time physical activity levels among blacks and whites in population-based samples: The Minnesota Heart Survey. *J Behav Med.* 14(i):1-9 (1991).

Hahn LP, Folsom AR, Sprafka JM, Norsted SW. Cigarette smoking and cessation behaviors among urban Blacks and Whites. *Public Health Reports.* 105(3):290-295 (1990).

Burke GL, Sprafka JM, Folsom AR, Luepker RV, Norsted SW, Blackburn H. Trends in CHD mortality, morbidity and risk factor levels from 1960 to 1986: the Minnesota Heart Survey. *Int. J. Epidemiol.* 18(6):901-909 (1989).

Anderson K, Keith 1, Norsted SW. Tuberculosis transmission in Washington State male correctional facilities. *CHEST* 89(6):817-821 (1986).

Norsted SW, Kozinetz CA, Annegers JF. Formaldehyde complaint investigations in mobile homes by the Texas Department of Health. *Environ Research* 37, 93-100 (1985).

Stock TH, Monsen RM, Sterling DA, Norsted SW. Indoor quality inside manufactured housing in Texas. Paper number 85-85.1. Proceedings of the 78th Annual Meeting of the Air Pollution Control Association, Detroit Michigan. June, 1985.

ABSTRACTS:

Kron J, Oliver RP, Norsted SW, Silka MJ. The automatic implantable cardioverter defibrillator (AICD) in young patients. 62nd Scientific Sessions, American Heart Association. New Orleans, LA. November 13-16, 1989.

Folsom AR, Burke GL, Sprafka JM, Luepker RV, Norsted SW, Blackburn H. Trends in coronary heart disease mortality, morbidity, and risk factors in a U.S. urban population, 1970 to 1985. Xth Congress of the European Society of Cardiology. Vienna, Austria. August 28-September 1, 1988.

Burke GL, Sprafka JM, Norsted SW, Goldman L, Luepker RV, Blackburn H. Plateauing trends in stroke morbidity, mortality, and blood pressure levels: the Minnesota Heart Survey. Society for Epidemiologic Research. Vancouver, British Columbia, Canada. June 15-17, 1988.

Burke GL, Folsom AR, Sprafka JM, Norsted SW, Crow RS, Edlavftch SA, Luepker RV, Blackburn H. Declining case fatality with increased myocardial infarction rates from 1970 to 1985: Minnesota Heart Survey. 28th Conference on Cardiovascular Epidemiology. American Heart Association. Santa Fe, New Mexico. March 17-19, 1988.

Sprafka JM, Folsom AR, Luepker RV, Burke GL, Norsted SW, Blackburn H. Declining cardiovascular disease risk factors from 1973 to 1986: the Minnesota Heart Survey. 28th Conference on Cardiovascular Epidemiology. American Heart Association. Santa Fe, New Mexico. March 17-19,1988.

MANUSCRIPTS:

Norsted SW. A Cross-Sectional Study of Human Symptomatology and Residential Formaldehyde Exposures. Doctoral Dissertation. Houston, Texas: University of Texas. School of Public Health. 1987.

Norsted SW. Polychlorinated Biphenyl Fact Sheet. Olympia, WA: Department of Social and Health Services, State of Washington. (1986).

Schuman LM, Straub CP, Mandel JS, Norsted SW, Sprafka JM. Evaluation of the Methods Used To Determine Potential Health Risks Associated With Organic Contaminants In The Great Lakes Basin. In, Assessment of Potential Health Risks Associated with Organic Contaminants in the Great Lakes Basin: Feasibility Study. Contract #EPA/R806282. Master's Thesis. Minneapolis, MN. University of Minnesota. Division of Epidemiology/Division of Environmental Health. 1982.